DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

OMB
Display Date 6-12-01
Publication Date 6-13-01
Certifier

[Docket No. 01D–0224]

Draft Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues." This draft guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. This draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

DATES: Submit written comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail:

NAD-1

fdadockets@oc.fda.gov. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David N. Heller, Center for Veterinary Medicine (HFV–510), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8156, e-mail: dheller@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) requires FDA to determine whether each new animal drug proposed for use in food-producing animals is safe and effective. In some cases, the new animal drugs used in food-producing animals have the potential to adversely affect the health of the humans who consume food derived from these animals. The sponsor of the new animal drug is responsible for establishing the safety of each new animal drug through appropriate tests.

To determine human food safety of new animal drugs, FDA evaluates the information/data, identifies and characterizes potential hazards, assesses exposure levels and characterizes the overall risk. Through this process, FDA establishes an allowable daily intake and tolerances (the amount of drug residue allowed in tissues) for each drug. Drug sponsors submit to FDA analytical methods that are designed to measure the concentration of the proposed drug in the edible tissues at the drug's tolerances. Analytical methods are used to monitor the tolerances set by FDA. FDA reviews the analytical methods during its review of new animal drug applications (21 CFR 514.1(b)(7)).

Analytical methods may also be used to monitor safe levels as established by the agency. Under section 512(a)(4)(B) of the act and 21 CFR 530.22, the agency may establish a safe level for extra-label use of a drug when the agency finds that there is a reasonable probability that an extra-label use may result in drug residues in edible tissue of the treated animals at a level that may present a risk to the public health if it was above the safe level. Under the same provisions,

FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level.

FDA issues guidance recommending methods of analysis to potential sponsors to foster timely and objective review of proposed new animal drugs, including the review of analytical methods. In the **Federal Register** of December 31, 1987 (52 FR 49589), FDA announced the availability of a set of eight guidance documents entitled "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals" (52 FR 49589); revisions to one of the guidances were announced in the **Federal Register** of July 22, 1994 (59 FR 37499). These guidances were designed to inform sponsors of the scientific data that FDA believes will provide an acceptable basis for determining the safety of such compounds, and for designing analytical methods.

Part V in the above-mentioned set of guidances, entitled "Guideline for Approval of a Method of Analysis for Residues," recommended that sponsors develop rugged methods of analysis designed to exceed rather than meet the minimal standards of acceptability. This serves two purposes: (1) To lower the number of method of analysis submissions that pass desk review but fail interlaboratory studies designed to test their effectiveness, and (2) to increase the precision and specificity of safety determination by ensuring a higher quality assay. The guidance then explained the evaluation criteria and data needed for approval of a method of analysis.

The draft guidance entitled "Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues" is designed to complement part V of "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals." The purpose of this document is to facilitate and expedite coordination between FDA's Center for Veterinary Medicine (CVM) and sponsors so the development, evaluation, and application of qualitative mass spectrometric methods will be completed in a consistent and timely manner.

This draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

This draft guidance should be used in the development of new methods, the review of methods submitted to CVM, and in the laboratory trial of methods submitted to CVM. The document also should help in making decisions about appropriate methodology in various regulatory situations and ensuring consistency in work done for CVM's purposes.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Information collection provisions described in this guidance have been approved under OMB control numbers 0910–0032 and 0910–0325.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Comments on the draft guidance may be electronically submitted at http:// www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Electronic copies of the draft guidance and other guidances discussed in this notice may be obtained at http://www.fda.gov/ cvm.

Dated: 5/30/01
5/30/01,

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S